

and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the directions, namely, "One tablet three times a day fifteen minutes before meals and at bedtime" and other similar directions borne on the labeling were not adequate directions for use.

DISPOSITION: March 7, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$500 against the defendant and placed him on probation for 1 year.

3388. Misbranding of male hormone tablets. U. S. v. Marvin Nashkin (Gold Seal Pharmacal Co.). Plea of guilty. Fine of \$250, plus costs. (F. D. C. No. 29432. Sample No. 57056-K.)

INFORMATION FILED: June 28, 1950, Northern District of Ohio, against Marvin Nashkin, trading as the Gold Seal Pharmacal Co., Cleveland, Ohio.

ALLEGED SHIPMENT: On or about November 28, 1949, from the State of Ohio into the State of New Jersey.

LABEL, IN PART: "Male Hormone (Methyl Testosterone) Regular Directions For use by adult males mildly deficient in male hormones when small dosages of male hormones are prescribed or recommended by a physician for palliative relief of such symptoms. Daily recommended intake of one light tablet provides 5 mg. of Methyl Testosterone in specially prepared base for sublingual use. Suggested Dosage One light tablet upon arising before breakfast. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying leaflet entitled "Attention! Men! Hormones" were false and misleading. The statements represented and suggested that the article would be of value to adult males mildly deficient in male hormones; that it would be of value to men beginning to feel past their prime; that it would constitute an adequate and effective treatment for diminished energy and vitality, worry over general health, depressed feeling, fatigue, irritability, excessive nervousness, and other common symptoms of the male climacteric; and that it would be efficacious in bringing men happiness and a longer useful life. The article would not accomplish the purposes claimed, and it would not constitute an adequate and effective treatment for the conditions so represented and suggested.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions, in that the directions for use borne on the labeling of the article were not adequate directions for use.

DISPOSITION: February 23, 1951. A plea of guilty having been entered, the court imposed a fine of \$250, plus costs, against the defendant.